IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Applicant:	David P. Witte, *et al.*	:	Docket No:	0010872/0482274
Serial No.	10/074,620	:	Group Art Unit:	1648
Filed:	February 13, 2002	:	Examiner:	Li, Bao Q.

For: **QUANTITATIVE EPSTEIN BARR VIRUS PCR RAPID ASSAY**

RESPONSE TO RESTRICTION REQUIREMENT

Mail Stop Non-Fee Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Office Action dated July 7, 2003, setting forth a restriction requirement under 35 U.S.C. § 121, please consider the following remarks:

The Examiner has now vacated the prior restriction/election of species requirement due to errors in the Detailed Action. Applicants appreciate Examiners clarification on this matter. The Examiner has now issued a new, corrected election/restriction and has requested that Applicants make an election, under 35 U.S.C. §121, to one of the following groups of claims that are alleged to constitute distinct inventions:

I. Claims 1-5, drawn to an composition (primers), said to be classified in class 536, subclass 24.33;

II. Claim 6, drawn to a method of detecting the presence of EBV DNA, said to be classified in class 435, subclass 6;

III. Claims 7-25, drawn to an method for amplification of the EBV DNA, said to be classified in class 435, subclass 91.1;

IV. Claims 26-30, drawn to a method of selecting an appropriate dosage or type of antiviral agent for treating an infection caused by EBV, said to be classified in class 435, subclass 173.1;

V. Claims 31-32, drawn to an method for the simultaneous amplification and detection of EBV, said to be classified in class 435, subclass 7.9; and

VI. Claims 33-39, drawn to a kit, said to be classified in class 435, subclass 975.

Applicants respectfully traverse this restriction requirement. First, it appears that except for Group I, the remaining groups of claims are all classified in the same class, that is, class 435. In this case, applicants request that claims of Groups II-VI, even if they were to represent independent or distinct inventions, the groups of these claims ought to be considered together based on MPEP §803. MPEP §803 indicates that even if an application contains more than one independent or distinct invention, those inventions ought to be considered together in the examination of the application provided such consideration does not place an undue burden on the Examiner. In addition, the patents reviewed in that search will, by necessity, include discussion of the primers described in Group I. These methods, at least to a significant extent, will overlap with the patents that would have to be searched for the claims relating to the primers themselves. Thus, searching the claims of Group I-VI together should not place an undue burden on the Examiner. For that reason, it is requested that the restriction requirement be withdrawn and that all claims currently pending in the current application be examined together.

Second, applicants contend that the six sets of claims defined by the Examiner are not drawn to distinct inventions. Group I defines a group of compositions (primers) which are utilized in each and every claim except claim 6. It is to be noted that all of the claims in

Groups III through VI expressly require the use of the same primers described in Group I and the same probes and described in Group II.

Further, even if one assumes *arguendo* that Groups I-VI represent independent or distinct inventions, all claims should still be considered together. MPEP §803 states that "[i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to distinct or independent inventions." If the method defined in Group III is elected by Applicants, a full search of those claims would necessarily include the primers and probes as described in Groups I and II and which are also used in Groups IV, V and VI. Also, a search relating to the primers described in Group I would clearly cover a great deal of art relating to the use of those primers in the methods and kits of the remaining Groups. In this case, because of the overlap in the search between the groups of claims defined by the Examiner, considering all claims together would not place an undue burden on the Examiner and, therefore, the Restriction Requirement is improper under the provisions of MPEP § 803 (even assuming that these groups represent independent or distinct inventions).

In the event the Examiner maintains the restriction requirement, **Applicants elect the claims of Group I** for further prosecution in the present application, reserving the right to prosecute the remaining claims in a separate divisional application.

Additionally, the Examiner contends that upon election of Group I, the applicant is additionally required to elect one pair primer sequences selected from (a) SEQ ID NO:1 and 2, or (b) SEQ ID NO:5 and 6 to be examined on the merits. The Examiner contends that this requirement is not to be construed as a requirement for an election of species, since each pair primer/probe is not a member of a single genus of invention, but constitute an independent and patentably distinct invention. Applicants respectfully traverse this restriction requirement.

Applicants contend that this restriction requirement is improper in that even if considered independent and patentably distinct inventions, the selection of primers and

probes are members of a Markush group. According to MPEP 803.02, if the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the Examiner must examine all the members of the Markush group in the claim on the merits (even assuming that these represent independent or distinct inventions). In such a case, the Examiner is not to require restriction. Applicants contend that the claims, in containing ***only two groups***, could not be considered a serious burden. Applicants have not submitted a bulk sequence listing of thousands of unrelated sequences. Finally, Applicants contend that the species of the two primer pairs are not patentably distinct inventions over each other.

For all of the above reasons, the restriction requirement defined by the Examiner is improper. Accordingly, it is respectfully requested that the restriction requirement be withdrawn. The Examiner is urged to reconsider the restriction/election requirement and either eliminate it entirely or at the very least redefine this as a composition (Group I), methods (Groups II-V) and a kit (Group VI), along with an election of species requirement for the primers and probes given the tremendous overlap of subject matter in the independent claims.

Furthermore, the Examiner has indicated that the application contains claims directed to patentably distinct species of the claimed invention and that applicant as required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, the Examiner considers Claims 9, 26 and 33 generic. Applicants hereby provisionally elect: Species A: (1) PCR; Species B: (a) thermostable polymerase; and Species C: (i) digoxigen-dUTP, respectively.

Applicants' undersigned attorney has made a good faith effort to be responsive to the restriction requirement made in the Office Action dated April 8, 2003. If the Examiner would like to discuss the restriction requirement or to have applicants provide any clarification of its terms, she is invited to contact Applicant's undersigned attorney at the phone number given below.

Appl. No. 10/074,620
Response dated Thursday, July 31, 2003
Reply to Detailed Action of July 7, 2003

Respectfully submitted,

WITTE, *et al.*

By _____

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SUZANNE C. LaRue
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Attn: Li, Bao Q.

Art Unit No.: 1648

Serial No. 10/074,620

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